K000316

FEB 24 2000

Attachment 4

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is:_____

A. Date of submission: January 28, 2000

B. Type of Submission: Special 510(k): Device Modification

C. Applicant's Name, Address

Meretek Diagnostics, Inc.
618 Grassmere Park Drive, Suite 20
Nashville, Tennessee 37211

D. Contact Person

Kerry Bush
Chief Operating Officer
Meretek Diagnostics, Inc.
618 Grassmere Park Drive, Suite 20
Nashville, TN 37211

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E. Product Information

1. Trade Name of the Device

Meretek UBT_Lite™ Breath Test for *H. pylori*

2. Common Name of the Device

Breath Test for *Helicobacter pylori*; UBT

3. Classification

Product Code: MSQ
Regulatory Class: Class II

F. Predicate Device Information

Trade Name: Meretek UBT™ Breath Test for *H. pylori*
510(k) number: K972352
510(k) clearance date: October 29, 1997

G. Description of the Device

The device is a combination diagnostic drug/device kit composed of the following principal components:

- Pranactin-Citric™ formulated diagnostic drug dosage
- Dosage cup
- Plastic straws
- Breath collection tubes

Principle of the Test

In the Meretek UBT_Lite™ Breath Test for *H. pylori*, Pranactin-Citric™ containing ^{13}C-urea is reconstituted with water then ingested by the patient. In the presence of urease associated with gastric *H. pylori*, ^{13}C-urea is decomposed to $^{13}CO_2$ and NH_4^+ according to the following equation:

$$(NH_2)_2{}^{13}CO + H_2O + 2H^+ \xrightarrow{HpUrease} {}^{13}CO_2 + 2NH_4^+$$

^{13}C-urea

The $^{13}CO_2$ is absorbed in the blood, then exhaled in the breath. This results in an increase in the ratio of $^{13}CO_2$ to $^{12}CO_2$ in a TEST breath sample compared to a BASELINE sample taken before the Pranactin-Citric™ solution was consumed. Analysis of the breath samples is performed by Gas Isotope Ratio Mass Spectrometry ("GIRMS") at Meretek's clinical laboratories or at other qualified laboratories licensed by Meretek Diagnostics, Inc.

H. Intended Use

The Meretek UBT_Lite™ Breath Test Collection Kit is intended for use in the qualitative detection of urease associated with *Helicobacter pylori* in the human stomach and as an aid in the initial diagnosis and post-treatment monitoring of *Helicobacter pylori* infection in adult patients. The test may be used for monitoring treatment if used at least four weeks following completion of therapy. For these purposes, the system uses a Gas Isotope Ratio Mass Spectrometer ("GIRMS") for the measurement of the ratio of $^{13}CO_2$ to $^{12}CO_2$ in breath samples.

For administration by health care professionals. To be administered under a physician's supervision.

I. Summary of Modifications

Component	Predicate Meretek UBT®	Meretek UBT_Lite™
Drug Component	♦ 125 mg ^{13}C-urea ♦ Dried powder	♦ Changed ^{13}C-urea content ♦ Formulated dosage with citric acid and inactive ingredients
Water for reconstitution	75 ml sterile water added to drug component	Potable water added to formulation in dose cup
Pre-test Fast	♦ Yes	♦ Yes
Pre-test Meal	Commercial pudding	No pre-test meal
Specimen collection method	♦ Plastic breath bag ♦ 4 evacuated test tubes	♦ Straws ♦ 4 evacuated test tubes
Specimen collection time (post-dose)	♦ 30 minutes	♦ Reduced collection time

J. Substantial Equivalence

The Meretek UBT_Lite™ Breath Test for *H. pylori* has the following similarities to the Meretek UBT® Breath Test for *H. pylori* which previously received 510(k) clearance:

1. Has the same intended use
2. Uses the same fundamental scientific technology
3. Uses the same diagnostic drug (^{13}C-urea) in aqueous solution
4. Includes a component to inhibit gastric emptying
5. Collecting breath directly gives the same results as Breath Bag collection.
6. Analyzes breath samples by the same method (Gas Isotope Ratio Mass Spectrometer), using the same equipment and quality control system
7. Calculates results by the same procedure
8. Uses the same cutoff value (2.4‰) to distinguish *H. pylori* negative *from H. pylori* positive patients
9. Gives substantially equivalent diagnostic results on adult test subjects.

K. Nonclinical Testing

A reproducibility/breath sample stability test was designed and executed with the following purposes:

1. To evaluate the site-to-site reproducibility of the UBT breath analysis (GIRMS) systems
2. To compare breath collection methods
3. To evaluate the stability of gas (breath) samples in breath sample tubes after air freight/ground transport and over time

Results

- The Gas Isotope Ratio Mass Spectrometers breath analysis systems used for the Meretek UBT® Breath Test and Meretek UBT_Lite™ Breath Test are reproducible.
- Direct Collection of breath specimens gives results equivalent to the standard Meretek Breath Bag technique.
- Breath or other gas specimens may be shipped by air and/or ground and are stable for the periods tested.

L. Clinical Testing

The method comparison data presented here were collected from a prospective, cross-over clinical field trial designed to validate the Meretek UBT_Lite™ test procedure and to examine the effect of pre-test fasting time on test performance. The study included 252 adult test subjects from Houston and Galveston, Texas. Subjects were judged to be in acceptable health based on the results of a medical history and physical examination and demonstrated no uncontrolled clinically significant abnormality other than, for some, symptoms of dyspepsia.

Method comparison results are presented in the two-way contingency table below. Relative Sensitivity, Relative Specificity and their corresponding 95% confidence intervals are listed below the table.

	Meretek UBT_Lite™ Results		
Meretek UBT®	**positive**	**negative**	**Total**
positive	105	1	106
negative	1	145	146
Total	106	146	252

Relative sensitivity: 99.1 % [95% CI: (94.9, 100.0)]
Relative specificity: 99.3 % [95% CI: (96.2, 100.0)]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

24 FEB 2000

Mr. Kerry Bush
Chief Operating Officer
Meretek Diagnostics, Inc.
618 Grassmere Park Drive
Suite 20
Nashville, Tennessee 37211

Re: K000316
Trade Name: Meretek UBT Lite™ Breath Test for *Helicobacter pylori*
Regulation Number: 866.3110
Regulatory Class: I
Product Code: MSQ
Dated: January 27, 2000
Received: February 1, 2000

Dear Mr. Bush:

This letter corrects our previously issued substantial equivalent letter of February 24, 2000, since your device has a drug component. We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

In addition, we have determined that your product contains the following component subject to regulation as drugs: Pranactin-Citric™-75mg.

Our substantially equivalent determination does not apply to the drug component (NDA 20-586/S004) of your product. For information on applicable Agency requirements for marketing this product, we suggest you contact:

Mark Goldberger, M.D., M.P.H.
Director
Division of Special Pathogens and Immunologic Drug Products
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
(301) 827-2336

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality Systems Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under section 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification although we recommend that you first contact the Center for Drug Evaluation and Research before marketing your drug component[s]. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice for your device on the labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), promotion, or advertising, please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-302) at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health